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10/510,229	10/13/2004	Yoram Reiter	28429	6861

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EXAMINER
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LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/510,229

Applicant(s)

REITER ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 141-160 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 141-160 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9-14-05.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 141-160 are pending and under consideration.

#### ***Election/Restrictions***

2. Applicant's election of the species wherein the targeted cell is an antigen presenting cell (APC) and wherein the antibody comprises the amino acids sequence of SEQ ID NO: 23 in the reply filed on October 10, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction between the APC and the species of claim 148 is withdrawn.

#### ***Priority***

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: the present application does not correctly include reference to the prior application 10/396,578 because the reference does not provide the relationship between the present application and the prior application. See e.g., MPEP 201.11 III.A. In order for the Applicant to be given benefit of the earlier filing date, the present application must be amended to properly identify the present

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application (or the WO application of which it is a national stage) as a continuation, divisional, or a continuation-in-part of the prior filed application.

Because the claim to priority was recognized in the filing receipt, no petition for a delayed claim of priority is required.

***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on September 14, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 141 and 144-160 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of using antibodies to kill or damage cells using the indicated antibodies where the antibody or fragment thereof is attached to a toxin, does not reasonably provide enablement for methods of killing or damaging cells merely through the exposure of the cells to the antibodies. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered. The factors considered most relevant in the present case are the guidance and direction presented, the state of the art, and the breadth of the claims.

As indicated above, the claims are drawn to a method for the killing or damaging of cells through exposing the cells to an antibody. Claims 142 and 143, not included in the rejection, require that the antibodies be attached to a toxin. The application indicates that cells may be killed using the antibodies attached to a toxin. Page 34, lines 21-24. However, the application also indicates that antibodies may also be attached to other functional moieties such that other, non-lethal, uses of the antibodies may be made. See e.g., pages 32-33. Thus, the teachings of the application indicate that the antibodies kill or damage cells when a toxin is attached thereto. However, because the application also teaches that the antibodies are useful for the detection and purification of cells, it thereby indicates that the antibodies themselves do not kill or damage the cells. This is because, if this were not the case, the antibodies would not be useful in the other methods such as in the detection or purification methods suggested by the application.

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In view of these teachings, representing both the guidance in the application and the state of the prior art, it would have been apparent to those in the art that the Applicant was not enabled for damaging or killing target cells merely through exposing them to the antibodies. Rather, the antibodies would first need to be attached to toxins capable of causing such damage or cell death before functional requirements of the claimed methods could be achieved. The claims are therefore rejected as exceeding the scope of enablement as the claims read on the use of any antibody, and not on the use of antibodies to which a toxin is attached.

7. Claim 150 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This claim reads on a genus of methods comprising the use of an antibody or fragment thereof that binds to a human antigen-presenting molecule/antigen complex wherein the fragment comprises the sequence of SEQ ID NO: 23.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

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A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed.

In the present case, the Applicant has disclosed only a single antibody comprising SEQ ID NO: 23 that is able to bind to one of the indicated complexes. The application provides no demonstration that the presence of SEQ ID NO: 23 is an antibody binding domain correlates with the antibody's ability to bind such a complex. Thus, the application has provided only a single working example of the claimed genus, and has not demonstrated any function/structure correlation with the required binding affinity and SEQ ID NO: 23.

The art relating to antibodies recognizes that the formation of an intact antigen-binding site generally requires the association of the complete heavy and light chain variable regions of a given antibody, each of which consists of three CDRs which provide the majority of the contact residues for the binding of the antibody to its target epitope. See e.g., Poljak et al., Philos Trans R Soc London [Biol] 272: 43-51 (teaching on page 44 that the variable domains of both the heavy and light chains are involved in determining antibody specificity); and Daugherty et al., Nuc Acids Res 19: 2471-76 (indicating that each of the CDRs from both chains of antibodies are required to maintain specificity in humanized antibodies). Thus the art teaches that the amino acid sequences and conformations of each of the heavy and light chain CDRs are critical in maintaining the antigen binding specificity and affinity that is characteristic of the parent immunoglobulin.

From these teachings, it is expected that all of the heavy and light chain CDRs in their proper order and in the context of framework sequences which maintain their required conformation, are required in order to produce a protein having antigen-binding function and that proper association of heavy and light chain variable regions is required in order to form functional antigen binding sites. Even minor changes in the amino acid sequences of the heavy and light variable regions, particularly in the CDRs, may dramatically affect antigen-binding function as evidenced by Rudikoff et al. (Proc Natl Acad Sci USA 79: 1979- of record in the September 2005 IDS). Rudikoff et al. teaches that the alteration of a single amino acid in the CDR of a phosphocholine-binding myeloma protein resulted in the loss of antigen-binding function. The teachings of the Poljak et al. reference (supra.) also teaches both that modifications to single amino acids in a variable region affects the structure of the antibodies active site- and thus its binding specificity, and that the structure of the active site may also be altered through different pairings of the heavy and light chains. Page 46. Thus, these references teach the uncertainty in the art as to the affects of any modification to the antibody sequences.

Further, the Poljak reference particularly indicates that the variable region of either a heavy or light chain may be included in antibodies with different active site structures, and therefore different binding specificities. Not only does this support the uncertainty in the art, but it also suggests the presence of a variable region from one antibody does not demonstrate that any antibody comprising that sequence would have the same binding specificity. In the present case, such can be seen with reference to SEQ ID NO: 23 due to its presence in at least two other antibodies having distinct binding activities from the antibody fragment T3F2, the MHC/antigen binding antibody fragment disclosed on page 72 in the present application. See



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e.g., Shiono et al., Int Immunol 15: 903 at 907 (disclosing the M11 anti-IFN $\alpha$  antibody fragment, comprising SEQ ID NO: 23 in the light chain variable region residues 24-35 as seen in GenPept AAO45455); and Shriner et al., Vaccine 24: 7197 at 7198 (disclosing the isolation of antibodies that bind to pneumococcal polysaccharides, including the antibody of GenPept ABG38407, having SEQ ID NO: 23 at positions 26-38 of the light chain variable domain). Thus, the art indicates that the present of SEQ ID NO: 23 in a variable light chain sequence of an antibody is not indicative of the antibodies ability to bind the complexes targeted by the present claims.

In view of these teachings, the limited provision of species in the application, and the lack of any demonstration that SEQ ID NO: 23 necessarily corresponds to the required functions, the claim is rejected as lacking sufficient written description support for the claimed genus of inventions.

### *Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 141-149, 151-155, 158, and 159 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiter as applied above, further in view of the teachings of Andersen et al., (WO 97/02342). Claims 141-144, 146-148, 151-153, 155, 158, and 159 are drawn to methods for killing cells comprising exposing the cells to an antibody or binding fragment thereof that binds

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to a complex of an MHC molecule and an antigen from a pathogen, wherein the antibody or fragment is attached to a toxin (esp. *Pseudomonas* exotoxin A or a portion thereof). Dependent claims further identify the antigen as from a virus, and indicate that the killed cell is infected with the virus. Claim 145 reads on methods wherein the cells are exposed to the antibody/toxin conjugate through administration of the conjugate to an individual. Claim 149 requires that the antibody fragment is an Fv fragment. Claim 154 reads on methods wherein the MHC molecule is an HLA-A2 molecule.

Reiter teaches a method of killing a B-cell infected with a virus by contacting the cell with an antibody that binds to an MHC molecule complexed with an antigen of the virus. Page 4635, right column. The Fab molecule described by the reference binds to a complex of an MHC class I molecule and a viral peptide. Page 4631. The reference teaches that the Fab was attached to a portion of the *Pseudomonas* exotoxin. Id. Thus, the reference teaches methods according to the indicated claims, except that the MHC-complexes targeted in the reference comprise murine, and not human, MHC molecules. While the reference does not actually kill such cells through administration of the conjugates to an individual, the reference does suggest that such conjugates may be used for the to develop therapeutic agents (albeit against cancers).

While the reference does not teach embodiments wherein the MHC in the targeted complex is a human MHC, the reference does suggest such embodiments. For example, on page 4631, the reference indicates that certain MHC-peptide complexes that may be targeted are complexes of HLA-A2 molecules with a peptide antigen. Thus, the reference suggests the use of antibodies (or fragments thereof) that target HLA-A2 complexes. Finally, while the reference does not actually kill such cells through administration of the conjugates to an individual, the

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reference does suggest that such conjugates may be used for the to develop therapeutic agents (albeit against cancers). Thus, the reference suggests the administration of such conjugates into an individual to kill a cell expressing an MHC/antigen complex.

However, while Reiter teaches the use of a Fab fragment, the reference does not teach or suggest the use of an Fv fragment as required by claim 149. Further, while the reference also suggests the use of antibodies targeting of HLA-A2 molecule complexes, the suggestion is directed to the treatment of cancers, not of viral or pathogenic infections as required by the present claims.

Andersen provides similar teaching to those of Reiter. See e.g., abstract, and pages 16 and 19-20. This reference indicates on pages 19-20 that the antibody conjugates may be used for the treatment of more than cancers, and specifically indicates that viral infections may also be targeted. The Andersen reference also teaches that the antibody or fragment thereof may be any of the operable antibody binding fragments, including Fv fragments. Pages 8-9. Because Andersen indicates that Fv fragments are functional equivalents of Fab fragments, it would have been obvious to those of ordinary skill in the art to use such fragments in the place of the Fab fragments suggested by Reiter. The Andersen reference also indicates that numerous MHC molecules are known in the art, and that the antibodies may be directed to complexes comprising any of such molecules. Pages 10-11. Thus, it would have been obvious to those of ordinary skill in the art to have used antibodies that target any viral peptide/MHC complex, including those of either the H-K<sup>k</sup> type as demonstrated in Reiter, or of other types including HLA-A2. The combined teachings of these references therefore render the claimed methods obvious.

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With respect to claim 158, it is noted that it is understood in the art that different peptide antigens are able to bind to different MHC molecules- i.e., the peptide antigens are inherently restricted by the antigen-presenting molecules to which it can bind. With respect to claim 151, it is noted that the references do not specifically indicate the dissociation constant of the disclosed Fab molecule. However, because the antibodies are being used as target specific carriers for therapeutic compounds, it would have been obvious to those of ordinary skill in the art to select antibodies with dissociation constants indicating that the antibodies would be so useful. Thus, the indicated range of such constants would have been obvious through routine optimization of the described methods. With respect to claim 144, it is noted that, while the Reiter reference does not specifically teach the isolation of a cell from an individual, the reference does indicate that the antibodies were derived from MHC molecules isolated from an isolated cell. As there is no indication in the claims when the cells were isolated relative to when they are exposed to the antibody/toxin conjugate, and because it would have been obvious to those of ordinary skill in the art to isolate the target cells from the individual such that antibodies directed against MHC complexes on that cell could be produced, the limitation claim 144 would have been obvious to those of ordinary skill in the art.

10. Claims 141-149 and 151-159 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiter and Andersen as applied above, further in view of the teachings of Matsushita et al. (U.S. 5,591,829- of record in the September 2005 IDS). Claims 156 and 157 further require that the pathogen infecting the target cell is a retrovirus, particularly a human T-cell lymphotropic virus type I (HTLV-1).

The teachings of Reiter and Andersen have been described above. While these references suggest the use of the indicated antibody conjugates to kill pathogen infected cells in general, and demonstrate the efficacy of the conjugates to kill virus infected cells, they do not specifically teach or suggest embodiments wherein HTLV-1 infected cells are targeted.

However, Matsushita teaches similar methods to those in Reiter and Andersen for the killing of retrovirally infected cells. While the reference uses antibodies targeting the pathogen antigens directly, instead of the MHC/antigen complex, from the teachings of Reiter regarding the virus infected cells, it would have been apparent to those of ordinary skill in the art that the antibodies of Reiter and Andersen (directed against complexes with a viral antigen) would be functional equivalents for the antibodies of Matsushita. Thus, it would have been obvious to those of ordinary skill in the art to modify the methods suggested by Reiter and Andersen for the treatment of HTLV-1 infections as suggested by the teachings of Matsushita. The combined teachings of these references therefore render the claimed methods obvious.

11. Claims 141-149 and 151-160 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiter and Andersen as applied above, further in view of the teachings of Saito et al. (J Virol 75: 1065-71- of record in the September 2005 IDS). Claim 160 requires that the antigen in the complex is a Tax protein polypeptide antigen. The teachings of Reiter and Andersen have been described above. As indicated above, these references cumulatively suggest the use of the indicated antibody conjugates to kill specific cells, including those expressing viral antigen/MHC complexes. However, the references do not specifically teach or suggest embodiments wherein the antigens are HTLV-1 antigens, or are Tax protein antigens.

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Saito teaches that, in certain HTLV-1 infected patients, cells comprising HLA-A2/Tax peptide complexes appear to be involved in the pathogenesis of the disease. Page 1070, left column. It is noted that the Tax peptide identified by Saito is the peptide of SEQ ID NO: 3. The reference teaches that such cells express an MHC/ viral peptide complex. From these teachings, those of ordinary skill in the art would have been motivated to kill these cells in the indicated subgroup of HTLV-1 infected patients. As the cells involved express the MHC/peptide complexes, and as the teachings of Reiter and Andersen suggest the use of antibodies targeting such complexes for the treatment of viral infections, it would have been obvious to those of ordinary skill in the art to make and use antibodies targeting the HLA-A2/Tax peptide complexes for use in methods of treating the HTLV-1 infections as suggested by Reiter and Andersen. Those of ordinary skill in the art would have had a reasonable expectation of success in the use of such antibodies in view of the teachings of Saito indicating that these cells were the cause of the pathogenesis in certain HTLV infections, and the demonstration and suggestion in Reiter and Andersen regarding the use of the antibodies to target MHC/peptide complex expressing cells. The combined teachings of these references therefore render the claimed methods obvious.

12. Claims 141-160 are rejected under 35 U.S.C. 103(a) as being obvious over Reiter, Andersen, and Saito as applied to claims 141-149 and 151-160 above, further in view of Hoogenboom et al. (U.S. 2003/0223994- of record in the September 2005 IDS). Claim 150 reads on embodiments wherein the antibody used in the method comprises the sequence of SEQ ID NO: 23.

As indicated above, the teachings of Reiter, Andersen, and Saito suggest a method for the treatment of HTLV-1 infection comprising the administration of an antibody attached to a toxin, wherein the antibody binds to a complex of the Tax peptide of SEQ ID NO: 3 with an HLA-A2 molecule. Such an antibody is disclosed in Hoogenboom. See e.g., page 35 (paragraph [0421 and Table 5), and Figure 19 (disclosing the sequence of the T3F2 antibody). Because the antibody of Hoogenboom performs the function of the antibody suggested by the combination of Saito with the teachings of Reiter and Andersen, it would have been obvious to those of ordinary skill in the art to use the antibody of Hoogenboom in the methods suggested by the other references. Thus, the combined teachings of these references render the claimed methods obvious.

The applied Hoogenboom reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

### *Double Patenting*

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 141-160 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 48-50 of copending Application No. 11/203,137, or the copending claims in view of the teachings of Reiter and Andersen in view of any of Hoogenboom, Matsushita, or Saito as applied above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims read on a species of the present claims, and would therefore anticipate (or in combination with Reiter, Andersen, and either Matsushita or Saito render obvious) the present claims if applied as prior art. The present claims are therefore either generic to, or represent an obvious variation from, the copending claims.



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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 141-160 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 8, 11, of copending Application No. 11/629194, or the copending claims in view of the teachings of Reiter and Andersen and Hoogenboom as described above. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims read on a species of the present claims, and would therefore anticipate (or in combination with Reiter, Andersen, and either Matsushita or Saito render obvious) the present claims if applied as prior art. The present claims are therefore either generic to, or represent an obvious variation from, the copending claims. .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

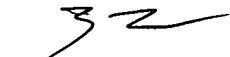
16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Z. Lucas  
Patent Examiner